

CLAIMS

We claim:

- 1) A method for remotely monitoring physiological parameters of a mammalian subject, whereby information obtained from sensors attached to said mammalian subject is transmitted by a communication means to a remote database management system and summarized to provide feedback to said mammalian subject or other authorized personnel, comprising the steps of:
 - a. providing at least one biointerface head attached to said mammalian subject, said biointerface head comprising at least one sensor for measuring physiological parameters;
 - b. said biointerface head communicating with at least one control and communication module attached to said mammalian subject;
 - c. transmitting data from said biointerface head to at least one control and communication module;
 - d. processing said data by the at least one control and communication module;
 - e. transmitting said processed data through a wireless means to at least one data collection unit;
 - f. transmitting data received by the at least one data collection unit to a remote database management system;
 - g. summarizing said data by said remote database management system; and
 - h. providing feedback of said summarized data to said mammalian subject or other authorized personnel through a communications means.
- 2) The method of Claim 1, further comprising the step of transmitting control instructions from the remote database management system to said data collection unit.

3) The method of Claim 2, further comprising the step of transmitting control instructions from said data collection unit to the control and communication module.

5 4) The method of Claim 3, wherein the control instructions are transmitted from the control and communication module to the biointerface head, enabling the release of therapeutic agents from said biointerface head.

10 5) The method of Claims 2 or 3, wherein the control instructions direct a visual or auditory signal to said mammalian subject.

15 6) The method of Claim 1, wherein the data from said biointerface head is received continuously by the control and communication module.

20 7) The method of Claim 1, wherein the data from said communication and control module is received continuously by the data collection unit.

25 8) The method of Claim 1, wherein the data from said biointerface head is received periodically by the control and communication module.

9) The method of Claim 1, wherein the data from said control and communication module is received periodically by the data collection unit.

10) The method of Claim 1, wherein the control and communication module conditions said transmitted data received from the biointerface head.

11) The method of Claim 1, wherein the control and communication module encrypts said transmitted data received from the biointerface head.

5 12) The method of Claim 1, wherein the control and communication module encodes said transmitted data received from the biointerface head.

13) The method of Claim 1, wherein the biointerface head is mounted to the body surface of said mammalian subject.

14) The method of Claim 1, wherein the biointerface head is implanted subcutaneously, or within the body of said mammalian subject.

15) The method of Claims 13 or 14, wherein the biointerface head is physically attached to the control and communication module.

16) The method of Claims 13 or 14, wherein the biointerface head is not physically attached to the control and communication module and said biointerface head communicates with the control and communication module through a wireless means.

17) The method of Claim 1, wherein the control and communication module serially transmits data to one or more remotely-located control and communication modules.

18) The method of Claim 1, wherein the control and communication module serially transmits data to one or more data collection units.

- 19) The method of Claim 1, wherein the control and communication module transmits data to at least two data collection units.
- 5 20) The method of Claim 1, wherein the data collection unit is attached to the mammalian subject.
- 21) The method of Claim 1, wherein the data collection unit is remotely located relative to the mammalian subject.
- 22) The method of Claim 1, wherein the data collection unit conditions said transmitted data received from the control and communication module.
- 23) The method of Claim 1, wherein the data collection unit amplifies said transmitted data received from the control and communication module.
- 24) The method of Claim 1, wherein the data collection unit is configured to allow data processing and storage for future transmission of said data to said remote database management system.
- 25) The method of Claim 24, wherein the data collection unit processes said data transmitted from the control and communication module and transmits an analysis of the data to said mammalian subject.

26) The method of Claim 25, wherein the evaluation of said data is displayed visually or through auditory means on said control and communication module.

27) The method of Claim 25, wherein the evaluation of said data is transmitted through a wireless means to a data transmission or telecommunications device.

28) The method of Claim 1, wherein the data collection unit is physically linked to the database management system for direct transfer of said data.

29) The method of Claim 1, wherein the communication means with said mammalian subject or other authorized personnel comprises a wireless means.

30) The method of Claim 29, wherein said wireless means is a telecommunications device allowing bi-directional visual or auditory communication with said mammalian subject or authorized personnel.

31) The method of Claim 29, wherein said wireless means is a data transmission device conveying visual or auditory signals informing said mammalian subject of the determined physiological status.

32) The method of Claim 1, wherein said feedback of summarized data to the mammalian subject is communicated through a computer network means.

33) A processor readable medium for tangibly embodying a series of instructions for performing the method steps of Claim 1.

34) The medium of Claim 33, which is selected from the group comprising a disk, RAM, ROM, and VRAM.

5 35) The medium of Claim 33, which is selected from the group comprising a hard disk, floppy disk, flash memory, and a compact disk.

36) A method for remotely monitoring physiological parameters of a mammalian subject, whereby information obtained from sensors attached to said mammalian subject is transmitted by a communication means to a remote database management system and summarized to provide feedback to said mammalian subject or other authorized personnel, comprising the steps of:

- a. providing at least one biointerface head attached to said mammalian subject, said biointerface head comprising at least one sensor for measuring physiological parameters;
- b. said biointerface head communicating with at least one control and communication module attached to said mammalian subject;
- c. transmitting data from said biointerface head to at least one control and communication module;
- 20 d. processing said data by the at least one control and communication module;
- e. transmitting said processed data through a wireless means to at least one data collection unit;
- f. transmitting data received by the at least one data collection unit to a remote database management system;
- 25 g. summarizing said data by said remote database management system;

- h. providing feedback of said summarized data to said mammalian subject or other authorized personnel through a communication means;
- i. transmitting control instructions in response to said summarized data from said remote database management system to said data collection unit; and
- 5 j. transmitting said summarized data from said data collection unit to the control and communication module attached to said mammalian subject.

37) The method of Claim 36, further comprising the step of transmitting said control instructions from the control and communication module to the biointerface head, enabling the release of therapeutic agents from said biointerface head.

38) The method of Claim 36, wherein the control instructions direct a visual or auditory signal on the control and communication module, which alerts the mammalian subject to the summarized data.

39) The method of Claim 36, wherein the control instructions direct a visual or auditory signal on the data collection unit, which alerts the mammalian subject to the summarized data.

40) The method of Claims 38 or 39, wherein the mammalian subject communicates bi-directionally with an authorized personnel through a wireless means in response to the visual or auditory signal.

41) A method for remotely monitoring physiological parameters of a mammalian subject, whereby information obtained from sensors attached to said mammalian subject is

transmitted by a communication means to a remote database management system and summarized to provide feedback to said mammalian subject or other authorized personnel, comprising the steps of:

- a. providing at least one biointerface head attached to said mammalian subject, said biointerface head comprising at least one sensor for measuring physiological parameters;
- b. said biointerface head communicating with at least one control and communication module attached to said mammalian subject;
- c. transmitting data from said biointerface head to at least one control and communication module;
- d. processing said data by the at least one control and communication module;
- e. transmitting said processed data through a wireless means to at least one data collection unit;
- f. transmitting said processed data received by the at least one data collection unit to a second data collection unit if no communication can be established with a remote database management system;
- g. repeating the transmission of said processed data received by the second data collection unit to additional data collection units until communication can be established with a remote database management system;
- h. summarizing said data received by said remote database management system; and
- i. providing feedback of said summarized data to said mammalian subject or other authorized personnel through a communications means.

42) A method for remotely monitoring physiological parameters of a mammalian subject, whereby information obtained from sensors attached to said mammalian subject is transmitted by a communications means to a remote database management system and summarized by said remote database management system to provide feedback to said mammalian subject or other authorized personnel, comprising the steps of:

- a. providing at least one biointerface head attached to said mammalian subject, said biointerface head comprising at least one sensor for measuring physiological parameters;
- b. said biointerface head communicating with at least one control and communication module attached to said mammalian subject;
- c. transmitting data from said biointerface head to at least one control and communication module;
- d. processing said data by the at least one control and communication module;
- e. transmitting said processed data through a wireless means to at least one data collection unit;
- f. serially repeating transmission of said data from said data collection unit to one or more remotely located data collection units until said processed data is relayed to one or more remote database management systems;
- g. summarizing said data by said remote database management system; and
- h. providing feedback of said summarized data to said mammalian subject or other authorized personnel through a communications means.

43) The method of Claim 42, wherein control instructions are transmitted from said remote database management system to the data collection unit.

44) The method of Claim 43, further comprising transmitting control instructions from said data collection unit to the control and communication module.

45) The method of Claim 44, wherein said control instructions are transmitted further to the biointerface head, enabling the release of therapeutic agents from said biointerface head in response to said summarized data of said mammalian subject.

46) A method for remotely monitoring physiological parameters of a mammalian subject, whereby information obtained from sensors attached to said mammalian subject is transmitted by a communications means to a remote database management system and summarized by said remote database management system to provide feedback to said mammalian subject or other authorized personnel, comprising the steps of:

- a. providing at least one biointerface head attached to said mammalian subject, said biointerface head comprising at least one sensor for measuring said physiological parameters;
- b. said biointerface head communicating with at least one control and communication module attached to said mammalian subject;
- c. transmitting data from said biointerface head to at least one control and communication module;
- d. processing said data by the at least one control and communication module;
- e. transmitting said processed data to a remotely located second control and communication module;
- f. serially repeating the transmission of said data from said remotely located second control and communication module to one or more remotely located

control and communication modules until said data is relayed to at least one remotely located data collection unit;

g. transmitting data received by the at least one data collection unit to a remote database management system; and

5 h. summarizing said data at the remote database management system.

47) The method of Claim 46, wherein control instructions are transmitted from said remote database management system to said data collection.

10 48) The method of Claim 47, further comprising transmitting control instructions from said data collection unit to the control and communication module in response to the summarized data of said mammalian subject.

15 49) The method of Claim 48, wherein the control instructions are transmitted further from the control and communication module to the biointerface head, enabling the release of therapeutic agents from said biointerface head in response to said summarized data of said mammalian subject.

50) A system for monitoring the physiological status of a mammalian subject comprising:

20 a. a biointerface head comprising at least one sensor for measuring physiological parameters;

b. a control and communication module which is linked to the biointerface head, whereby said control and communication module processes data from the biointerface head and converts, conditions and encrypts said data;

- c. at least one data collection unit which receives data from the control and communication module; and
- d. a remote database management system which receives data from the at least one data collection unit and processes said data.

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51) The system of Claim 50, wherein said database management further transmits control instructions to said data collection unit.

52) The system of Claim 50, wherein the biointerface head further comprises a chamber which releases one or more therapeutic agents in response to instructions transmitted by the database management system.

53) The system of Claim 50, wherein the data collection unit further directs a visual or auditory signal to said mammalian subject.

54) The system of Claim 50, wherein said biointerface head is mounted to the body surface of said mammalian subject.

55) The system of Claim 50, wherein said biointerface head is implanted subcutaneously, or within the body of said mammalian subject.

56) The system of Claim 50, wherein said sensor is selected from the group comprising thermal sensors, electrical sensors, optical sensors, chemical sensors, enzyme-linked sensors, radiation sensors, magnetic sensors, and physical sensors.

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57) The system of Claim 50, wherein said biointerface head is implanted subdermally and comprises:

- a. an external mounting ring;
- b. a transdermal conduit comprising the sensor assembly; and
- c. a sensor mounting head containing a biofluid access port.

58) The system of Claim 57, wherein said biointerface head is attached to said mammalian subject with biosynthetic adhesives.

59) The system of Claim 58, wherein said biosynthetic adhesives contain one or more of the groups comprising: growth factors, adherence molecules, adherence attractants or factors which promote the cutaneous wound-healing mechanism and formation of an epithelial-like structure around the mounting ring.

60) The system of Claim 57, wherein the transdermal conduit and biofluid access port is coated with hydrogel material.

61) The system of Claim 57, wherein the transdermal conduit contains a hydrogel material.

62) The system of Claims 60 or 61, wherein the hydrogel material contains preservatives, anti-inflammatory agents, antibiotics or antimicrobial agents.

63) The system of Claims 60 or 61, wherein the hydrogel material contains a chemical, compound or molecule for calibration of the sensor.

64) The system of Claim 57, wherein the transdermal conduit contains a fluid material containing preservatives, anti-inflammatory agents, antibiotics or antimicrobial agents.

5 65) The system of Claim 50, wherein the control and communication module comprises at least one of the following data processing components: signal receiver from the BIH assembly, filter system, memory buffer, analog to digital (A/D) conversion, error diagnosis and correction, data identification coding, power supply, power supply control, reception/transmission protocol, internal time reference and a transmitter means to convey the digitized data to the data collection unit.

66) The system of Claim 50, wherein the control and communication module encrypts the data and device identification information from the biointerface head.

15 67) The system of Claim 50, wherein the control and communication module comprises a feedback device.

20 68) The system of Claim 67, wherein the feedback device is selected from the group comprising light emitting diodes, piezo beepers, mechanical vibrators and mechanical clickers.

25 69) The system of Claim 67, wherein the display device is selected from the group comprising liquid crystal displays, organic light emitting diode displays, magnetically reactive polymer displays, passive or active colorimetric displays and color based alert displays.

- 70) The system of Claim 67, wherein the feedback device comprises a bi-directional communications means for auditory or visual communication between said mammalian subject and other authorized personnel.

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- 71) The system of Claim 70, wherein the bi-directional communications means is a wireless telephone or pager system.

- 72) The system of Claim 50, wherein the mammalian subject is a laboratory animal.

- 73) The system of Claim 72, wherein the biointerface head comprises at least one sensor for measuring at least one of the following physiological parameters: temperature, respiration, heart rate or blood pressure.